VAIRRS Workflow for Creating a New Project

1. Log into gov.irbnet.org with your username/password or PIV card
2. Select “Create a New Project” on the left hand side of the screen
3. Fill out the PI name, title, and any other relevant information. Select continue.
4. Under the “Select a Library” drop-down menu, choose “VAAAHS Research and Development Committee”
5. Click on “Initial FCOI\_OGE\_Form\_450\_Alternative\_VA\_032414a” to download the Conflict of Interest (COI) fillable PDF
   1. A COI form needs to be completed for all investigators and co-investigators
   2. Signed COIs should be emailed to [VAAAHSCOICommittee@va.gov](mailto:VAAAHSCOICommittee@va.gov)
   3. The COI Committee will review and, if approved, will forward signed COIs to the Research and Development Committee. If unable to approve, COIs will be routed for additional review.
6. Select the “start a wizard” button
7. Then select “VA- Project Cover Sheet”
8. Please fill out the questions…see below for helpful hints
   1. Contracts/Agreements: These can include CRADAs (this may be relevant if you project is administered by VERAM), MTAs, DUAs, or a contract for services. Please note that even if these are not selected, it may be deemed necessary during PO or ISSO review.
   2. Personnel: Where it says VA email address, please enter the preferred email address of the personnel
   3. When you have completed the questions, VAIRRS will generate a list of additional required documentation (some of it is redundant). Please refer to this list to ensure that you have attached the required documents.
   4. Select “Save and exit”
9. Under the “Designer” tab in the “Project Administration” section, you can continue to add required documents. Templates for standard forms will be available in the “Forms and Templates” section. Use the VAAAHS libraries. **The following documents should be included:**
   1. Scientific narrative (no template)
   2. DMAP (in Research and Development Committee library: d. VA\_DMAP.pdf)
   3. Budget (no template)
   4. Clinical Impact Form (in Research and Development Committee library: c. ASSESSMENT OF CLINICAL IMPACT ON VAAAHCS\_111720)
   5. LOS from supervisor (or they can sign-off in VAIRRS)
   6. Biosketches for PIs/Co-Is (for projects seeking approval to submit for grant funding)
   7. Subcommittee documents as applicable:
      1. For projects requiring IRB approval, see step 10.
      2. For projects requiring safety approval, include Form 10-0398 (in Subcommittee for Research Safety library: 10-0398 VA Ann Arbor Hazard and Safety Assessment)
      3. For projects requiring use of animals, include the ACORP (in Institutional Animal Care and Use Committee library: Animal Component of Research Protocol (ACORP))
10. If your project requires IRB review, you will also need to select the “Start a Wizard” button and select “VA-IRB Information Sheet”. When complete, this will be added to your documents.
    1. You will also need to upload protocols, consent forms, questionnaires, recruitment scripts, and any other relevant documents. See [**00. IRB Submission Guidance\_VAAAHS\_122320**](https://gov.irbnet.org/release/export/download.jsp?libId=45310) in the Document Library for additional information
11. Under “Project Administration” select “Share this project”
    1. The project must be shared with all members of your study team. This will allow their training to be linked to the study. The type of access is up to the PI/study team.
    2. In order to obtain the PI’s supervisor’s signature, the project should be shared with the supervisor (an account in IRBNet is necessary before sharing can take place). In the comments section, include a note indicating that they should sign the package, because this is the only way they will know to do that. Alternatively, the supervisor or department head could also include a LOS in the package to indicate their support.
12. In the “Designer” workspace, under the table of documents, select “Link/Unlink Training Records”. Select the training and credentials that are needed to be linked for each person on the study team by checking the box on the left. Select “Save” to add the training.
13. Under “Project Administration” select “Sign this Package”
    1. The PI should follow the instructions to sign off
14. Under “Project Administration” select “Submit this Package”
    1. Select VAAAHS Research Administration
    2. Click continue
    3. From the drop-down menu, select submission type as “New Project” for either human research, animal research, or safety research. It is okay if your project applies to more than one of those categories, just select the most relevant.